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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/587,525  | 09/08/2006  | Albertus Alard Dijk  | 4662-228            | 9517             |
| 23117 7590 09/24/2009<br>NIXON & VANDERHYE, PC<br>901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| BADR, HAMID R   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1794  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/587,525

**Applicant(s)**

DIJK ET AL.

**Examiner**

HAMID R. BADR

**Art Unit**

1794

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/86)  
Paper No(s)/Mail Date 7/27/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Sequence ID No. 3***

While Sequence ID No. 3 has been claimed, it appears that this amino acid sequence has not been submitted by the Applicants.

### ***Use Claims***

1. Claims 1-9 provide for the use of carboxypeptidase, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite for "the flavor development". Since the development and the type of flavor are not explained by the claims nor is there any guidance in the specification, it is unclear what is meant by this phrase.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 4-5 recite the broad recitation "fermented food", "the ratio of endoprotease activity to carboxypeptidase activity less than 0.01" and "carboxypeptidase is CPD-1" respectively, and the claims also recite "cheese", the ratio of endoprotease activity to carboxypeptidase activity less than 0.0005" and "CPD-1 having the amino acid sequence of SEQ ID No. 3" respectively which is the narrower statement of the range/limitation.

6. Claim 9 is indefinite for "for flavor generation". It is not clear what type of flavor and on what conditions it is generated. It is unclear what is meant by this phrase.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blinkovsky et al. (1999, Purification, characterization and heterologous expression in *Fusarium venenatum* of a novel serine carboxypeptidase from *Aspergillus oryzae*; hereinafter R1).
9. R1 discloses the role of carboxypeptidase in the liberation of amino acids in bitter peptides. R1 also discloses that serine carboxypeptidases are widely distributed in filamentous fungi. R1 also discloses that these carboxypeptidases are exopeptidases that specifically release amino acids from the C-terminal of peptides and proteins. R1 also disclose that such carboxypeptidases cause no internal cleavage of peptides. (page 3298, left hand column). The isolation and characterization of serine carboxypeptidases (CPD-I and CPD-II ) from *Aspergillus niger* are also known in the art.
10. Given that R1 discloses that these carboxypeptidases do not internally cleave proteins and peptides, it is clear that the ratio of endoprotease activity to the carboxypeptidase activity will be the same as the presently claimed ratios.

11. Given that R1 discloses a pure carboxypeptidase, it is clear that the carboxypeptidase activity will be due to a single enzyme as presently claimed.
12. R1 discloses that the ability of carboxypeptidase to release all C-terminal amino acids and the high specific activity makes it a promising candidate for use in production of protein hydrolysates and in flavor improving processes in the food industry.
13. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to add a carboxypeptidase to cheese for flavor improving properties. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in incorporation a carboxypeptidase into cheese.
14. **Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Transfiguracion et al. (1998, Purification and characterization of a carboxypeptidase Y from *Kluyveromyces fragilis* JSB95; hereinafter R2).**
15. R2 discloses that carboxypeptidase catalyzes the sequential hydrolytic liberation of amino acids from the carboxy terminal of peptides and proteins. (page 647, left hand column, Introduction).
16. R2 discloses that carboxypeptidase from yeast has been used extensively for the preparation of food protein hydrolysates in addition to more traditional cheese making applications. R2 discloses that more recently, carboxypeptidase has been gaining popularity for the accelerated ripening of cheese. (page 647, right hand column, the first few lines). The isolation and characterization of serine carboxypeptidases (CPD-I and CPD-II ) from *Aspergillus niger* are also known in the art.

17. Given that carboxypeptidase sequentially liberates the amino acids from the carboxy terminal of peptides and proteins, it is clear that the ratio of endopeptidase activity to the carboxypeptidase activity is the same as the presently claimed ratio.
18. Given that carboxypeptidase, as disclosed by R2, has been involved in the accelerated ripening of cheese, it is clear that it helps improve the flavor of cheese.
19. Given that the carboxypeptidase as disclosed by R2 is a purified enzyme (216 folds, see Abstract), it is clear that the carboxypeptidase activity will be by a single enzyme as presently claimed.
20. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to incorporate a carboxypeptidase into cheese for accelerated ripening, as taught by R1. One would do so to accelerate the ripening process of cheese and improve the cheese flavor in a shorter period of time. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in adding carboxypeptidase to cheese to improve flavor.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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